US ERA ARCHIVE DOCUMENT



Biopesticides Registration Improvement Course

Non-Conventional Pest Control Products - Classification

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Overview

- Sources of Information for Non-Conventional Pest Control Products, including Microbials, Pheromones and other Semiochemicals
- Classification Process
- Comparison with U.S. EPA Approach
- Areas for Improvement



Sources of Information

- Guidelines for the Registration of Non-Conventional Pest Control Products, PRO2010-06
 - Consultation period closed at the end of February 2011
 - Directive to be published in 2011-2012
- Guidelines for the Research and Registration of Products Containing Pheromones and Other Semiochemicals, PRO2002-02



Sources of Information

 Guidelines for the Registration of Microbial Pest Control Agents and Products, DIR 2001-02



Classification of Non-Conventional Pesticides

- Classification ≠ Designation
 - Outcome of classification is to determine the MOSP¹ class (timelines, fees); eligibility for review under these guidelines
 - Products must have certain characteristics
 - Once a classification is made, data requirements are determined as appropriate
 - Flexibility in addressing information requirements

1 Management of Submissions Policy



 Products eligible for consideration under these guidelines must have some, but not necessarily all, of the following characteristics:



- Low inherent toxicity to non-target organisms.
 - Products with low inherent toxicity to humans and other non-target organisms would be expected to have minimal environmental and health risks even if exposure is extensive.
 - Substances with chronic toxicity, carcinogenicity, genotoxicity, neurotoxicity, reproductive/developmental effects, or that metabolize into compounds of toxicological concern are not eligible for review under this proposal



- Low potential for their use to result in significant human or environmental exposure.
 - When exposure is negligible, risks may be minimal even if the product has some inherent toxicity

Not persistent in the environment.



- Already widely available to the public for other uses, with a history of safe use under conditions posing equivalent potential for exposure to humans and the environment.
- Non-toxic mode of action.
 - Pesticidal action that is not the result of toxicity to the target organisms, e.g., products that work by attracting, repelling, desiccating, or smothering pests





Unlikely to select for pest resistence.



Substances eligible for review under this guideline could include:

- Food items, preservatives or additives (e.g., crushed garlic, garlic powder, table salt, citric acid)
- Plant extracts and oils (e.g., vegetable and mineral oils)
- Commodity chemicals (e.g., acetic acid)
- Fertilizer or other plant growth supplements commonly used in the agricultural sector (e.g., mineral salts)
- Inert materials (e.g., diatomaceous earth)



Who determines if a substance meets the characteristics of a Non-Conventional Pest Control Product:

- Screening Officers identify when an applicant is requesting eligibility for review under PRO2010-06 or when clarification is needed
- Committee of representatives from EAD, HED, CES, VSAD, RD, PCRAD
- Rationale presented and Committee makes determination



Definition of Pheromones and SemiochemicalsArthropods only

A pheromone is a semiochemical produced by individuals of a species that affects the behaviour of other individuals of the same species.

A semiochemical is a message-bearing substance produced by a plant or an animal or a synthetic analogue of that substance which invokes a behavioural response in individuals of the same or other species.



Comparison with U.S. EPA Approach

Non-Conventionals

PMRA considers U.S. EPA classification for biopesticides

 PMRA's definition could also include inerts, inorganic substances, unique products where tiered data requirements could also apply



Areas for Improvement

Non-Conventionals

- Rationales for how an active ingredient meets the classification criteria
 - Quality of rationales is variable and could be improved
 - Include details of the use pattern, label claims, and as much scientific evidence as possible
 - Present a history of other uses of the substance







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